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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,674

02/17/2006

Kristine G. Koski

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1059 7590 06/29/2011
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EXAMINER

ROY, BAISAKHI

ART UNIT

PAPER NUMBER

3777

MAIL DATE

DELIVERY MODE

06/29/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,674	Applicant(s) KOSKI ET AL.	
	Examiner BAISAKHI ROY	Art Unit 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-15, 24-26, 36, 38-40, 42 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-15, 24-26, 36, 38-40, 42 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's IDS submission filed on 3/31/11 has been entered.

Allowable Subject Matter

2. Prosecution on the merits of this application is reopened on claims 1-10,13-15,24-26,36,38-40,42 and 47-49 considered unpatentable as shown in the rejections below.

3. Applicant is advised that the Notice of Allowance mailed September 16, 2010 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3777

Claims 1, 3-10, 13-15, 24-26, 36, 38-40, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanayama (20040267139) in view of Rosenfeld et al. (20040197930). Kanayama discloses a method and apparatus for sensing the inside of the uterus where the inside of the uterus is continuously monitored by a non-invasive method to detect intrauterine status of oxygenation to predict the risk of developing a medical condition in the pregnant mother or offspring based on a predetermine correlation between spectra of amniotic fluid and the risk of developing the medical condition [0009]. The method involves providing an optical spectrometer or detecting unit 1 for sensing the inside of the uterus using near-infrared light, an optical coupler or light-emitting fibers adapted to arrange the detecting unit with respect to the pregnant mother's uterine cervix or indirectly to the maternal abdominal wall and emits near-infrared light and the reflected light is detected by the light-receiving fibers at the detecting unit [0016, 0017]. Therefore the optical coupler or fibers are adapted to arrange the optical spectrometer with respect to the pregnant mother's amniotic sac to acquire information on the uterine cervix in situ without insertion of the instrument in the amniotic sac. Therefore the optical coupler is comprised within an endo-vaginal probe and the probe may function as an ultrasound device [0009]. The optical coupler comprises an optical source or light-emitting fibers and light-receiving fibers at the detecting unit [0017]. The process is non-invasive since it measures the uterine environment through the cervix to determine fetal growth retardation in the uterus [0042]. Kanayama teaches constant monitoring of the measurements to effectively monitor fetal condition [0042].

Kanayama does not explicitly teach of a spectrum. In the same field of endeavor Rosenfeld et al. teach of an apparatus and method for analyzing amniotic fluid by creating a

Art Unit: 3777

spectrum or proteomic profiles of biological fluids such as amniotic fluid and maternal serum enabling the diagnosis, prognosis, and monitoring of various pathological fetal/maternal conditions [0013-0023]. Rosenfeld et al. teach the use of a spectrometer (fig. 4, 14, 15, [0107]) to create a spectra of the fluid [0149-0157]. For human studies Rosenfeld et al. teach measuring various markers in amniotic fluid and ultrasound imaging, and amniocentesis is performed during the first trimester as a intervention in light of any risks associated with the pregnancy (col. 17 lines 36-61). It is well known to conduct measurements and monitor the pregnancy period effectively during each of the three trimesters. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Rosenfeld et al. to modify Kanayama to provide an effective spectral profile of the fluid to evaluate conditions.

5. Claims 2 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanayama in view of Rosenfeld et al. and further in view of Khoury et al. Kanayama and Rosenfeld et al. teach the use of a spectrometer for measuring the markers but do not teach the use of a Raman spectrometer. In the same field of endeavor Khoury et al. disclose a system and method for analysis of biological fluids including amniotic fluids (col. 2 lines 16-19). Khoury et al. also teach the use of a Raman spectrometer (col. 2 lines 46-49). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Khoury et al. to modify Kanayama and Rosenfeld et al. such that the markers in the amniotic fluid flowing through the abdominal wall are analyzed in a fast and efficient manner for the recognition of materials or compounds that are indicative of birth disorders.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (9:00 a.m. - 5:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR
/B. R./
Examiner, Art Unit 3777

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777